



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0509]

Agency Information Collection Activities; Proposed Collection; Comment Request; Appeals of Science-Based Decisions Above the Division Level at the Center for Veterinary Medicine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements for appeals of science-based decisions above the division level at the Center for Veterinary Medicine (CVM).

DATES: Submit electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRASaff@fda.hhs.gov](mailto:PRASaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Appeals of Science-based Decisions Above the Division Level at CVM--21 CFR Part  
10.75 (OMB Control Number 0910-0566)--Revision

Respondents: Respondents to this collection of information are applicants that wish to submit a request for review of a scientific dispute.

CVM's Guidance for Industry #79--"Dispute Resolution Procedures for Science-based Decisions on Products Regulated by the Center for Veterinary Medicine," describes the process by which CVM formally resolves disputes relating to scientific controversies. A scientific controversy involves issues concerning a specific product regulated by CVM related to matters of technical expertise and requires specialized education, training, or experience to be understood and resolved. Further, the guidance details information on how the Agency intends to interpret and apply provisions of the existing regulations regarding internal Agency review of decisions. In addition, the guidance outlines the established procedures for persons who are sponsors, applicants or manufacturers, for animal drugs or other products regulated by CVM, that wish to submit a request for review of a scientific dispute. When a sponsor, applicant, or manufacturer has a scientific disagreement with a written decision by CVM, they may submit a request for a review of that decision by following the established Agency channels of supervision for review.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
10.75	2	4	8	10	80

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

CVM encourages applicants to begin the resolution of science-based disputes with discussions with the review team/group, including the Team Leader or Division Director. The Center prefers that differences of opinion regarding science or science-based policy be resolved between the review team/group and the applicant. If the matter is not resolved by this preferred method, then CVM recommends that the applicant follow the procedure in Guidance for Industry

#79. Of the two respondents who were advised on the procedure during the past 3 years, one has not followed up to initiate it and the other is working with the review team/group to resolve the issue(s). Therefore, this estimated annual reporting burden is based on CVM's previous experience in handling formal appeals for scientific disputes.

Dated: October 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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